

Navigation Sciences, Inc.

Category:

Best Startup

Company Name:

Navigation Sciences, Inc.

Turnover and/or Funding:

Navigation Sciences has successfully raised approximately \$5.5 million from family offices and high-net-worth individual investors. The Series A round had a pre-money valuation of \$9.1 million and a post-money valuation of \$11.4 million. Recently, the company closed \$3 million of a \$5 million round, with a pre-money valuation of \$16.5 million. Currently, Navigation Sciences is seeking an additional \$2 million to implement workflow product enhancements, improve the user interface, advance software development, bolster the quality system, submit a 510(k) application, and fund a post-market clinical study.

Sub-Category:

Medical Technology / Digital Health

Corporate history (creation, key milestones, main funding,...)Information on Condition / Disease and need for solution / product (prevalence, existing treatments / solutions):

The underlying technology for the NaviSci System was developed at Brigham & Women's Hospital (BWH) by the company's scientific founders, Raphael Bueno, M.D., Chief of Thoracic Surgery, and Jayender Jagadeesan, Ph.D., Associate Professor of Radiology at the hospital and Harvard Medical School. The company holds the exclusive worldwide license to the patents and intellectual property from the hospital covering the technology and has filed additional patent applications. To date, four U.S. patents have been issued: the parent patent covering the NaviSci System for tissue resection with real-time margin measurement; a continuation-in-part patent that covers technology for determining margin measurement while compensating for soft tissue deformation during procedures such as lung, liver, thyroid, brain, and head and neck surgeries; and a patent covering bronchoscopic delivery of the fiducial marker.

Navigation Sciences has raised approximately \$5.5 million from family offices and high-net-worth individual investors. Recently, the company closed \$3 million of a \$5

million round with a pre-money valuation of \$16.5 million. The company is currently seeking an additional \$2 million to implement workflow product enhancements, improve the user interface, advance software development, bolster the quality system, submit a 510(k) application, and fund a post-market clinical study.

The NaviSci System recently completed a 25-patient prospective clinical feasibility study in patients with early-stage lung cancer. The study was designed to support a submission to the U.S. Food and Drug Administration (FDA) for U.S. market clearance. The results confirmed that the NaviSci System is functional in providing real-time margin assessment for the surgical resection of lung nodules, demonstrating its safety and effectiveness, and that the system's distance measurements strongly correlate with pathology lab results. An abstract has been submitted to present the data at a major medical conference in January 2023.

Each year, approximately 500,000 cases of soft tissue cancer in the U.S. could benefit from Navigation's technology. These include cancers of the lung, liver, head and neck, thyroid, brain, and breast. The addressable U.S. market for Navigation's technology, encompassing both systems and consumables, is estimated at around \$1.26 billion. The company's primary focus is on lung cancer, where early-stage detection and removal can significantly improve outcomes, and delayed treatment has a substantial impact on morbidity and mortality.

Currently, there are more than 69,000 cases of early-stage lung cancer in the U.S. that could potentially be treated using the NaviSci system, a number expected to rise to 92,000 by 2028. While the total number of lung cancer cases has been decreasing, the number of early-stage diagnoses is increasing annually. In 2017, 40 percent of lung cancer cases diagnosed were at Stage 1 and Stage 2. By 2028, it is estimated that nearly 60 percent of diagnosed lung nodules will be at Stage 1.

History of the development of the solution/product (Intellectual Property, preclinical and clinical datas, development collaborations):

The emergence of low-dose CT scanning in high-risk lung cancer populations as the standard of care is increasing the detection of small, early-stage lesions, creating the opportunity for potentially curative surgery. The detection of small tumors is also enabling the use of surgical approaches, such as wedge resection and segmentectomy, which remove less normal lung tissue and conserve lung function compared to complete lobar resection. While the choice of surgical approach depends on various factors, smaller tumors typically allow for less invasive methods. For these procedures, achieving the appropriate tumor margin is critical to preventing recurrence. Multiple studies have demonstrated that proper margins are key determinants of cancer recurrence.

Navigation Sciences' co-founder, Dr. Raphael Bueno, and his team at Brigham and Women's Hospital have been leaders in defining optimal surgical margins and resections in lung cancer. For instance, a study published in the Journal of Thoracic and Cardiovascular Surgery by Dr. Bueno and colleagues found that for non-small cell lung cancer tumors less than or equal to 2 cm, the local recurrence risk during wedge resection was decreased with margins of less than or equal to 15 mm.

Determining the appropriate margins during lung cancer surgery, as well as in other soft tissue procedures, presents a significant challenge to surgeons. Currently, tumors are imaged before surgery using CT while the lung is inflated; however, during surgery, significant tissue deformation occurs as the lung is deflated, and tissue is often displaced. This deformation makes it challenging to accurately determine the margins required to ensure complete tumor resection and minimize the risk of recurrence.

Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition:

The NaviSci™ Intelligent Surgical System is an innovative device that combines Augmented Reality (AR) and advanced software with surgical hardware to provide real-time in-vivo margin measurement, a breakthrough in surgical precision. This innovation allows surgeons to achieve optimal tumor margins during resection, significantly reducing the risk of cancer recurrence while preserving tissue. The system's ability to provide a 'GPS' for surgeons, offering precise tumor localization and real-time margin assessment, transforms the way soft tissue tumors are treated. Broadly, this technology paves the way for future research into minimally invasive surgical techniques and enhanced imaging technologies, potentially extending its applications beyond lung cancer to other types of cancers. By improving surgical outcomes, reducing recurrence risks, and preserving organ function, the NaviSci™ System has the potential to enhance the quality of life for countless patients, ultimately contributing to longer, healthier lives.

Please provide appropriate references (PubMed, Abstract, Website):

<https://navigationsci.com/>

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4539147/>

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7383497/>

<https://www.cancer.gov/news-events/cancer-currents-blog/2023/early-stage-lung-cancer-sublobar-surgery>

<https://www.nejm.org/doi/10.1056/NEJMe2215647>

<https://www.nejm.org/doi/full/10.1056/NEJMoa2212083>

<https://www.norc.org/content/dam/norc-org/pdfs/State-Specific%20PCDSs%20chart%201213.pdf>

<https://pubmed.ncbi.nlm.nih.gov/23697514/>

<https://jamanetwork.com/journals/jama/fullarticle/2777244>

<https://acsjournals.onlinelibrary.wiley.com/doi/full/10.3322/caac.21811>

<https://pubs.rsna.org/doi/10.1148/radiol.231988>

References File Document upload:

[Navigation Sciences PPT 20250412.pdf](#)

[NaviSci_WhitePaper_2_18_25.pdf](#)

[NaviSciExecSummary4_4_25C.pdf](#)